REMARKS/ARGUMENTS

The Examiner objected to claim 3 as including an obvious grammatical error. This matter has been corrected in the manner noted by the Examiner.

The Examiner rejected claims1 to 6, 8 to 12, 16 to 18 and 23 to 25 under 35 USC 112, first paragraph, on the basis that the specification, while enabling for the use of Bacillus Calmette-Guerin (BCG) for the therapeutic treatment of condylomata acuminata, does not reasonably provide enablement for the use of all *Mycobacterium* species/strains for the therapeutic treatment of all disease conditions caused by papilloma virus infection.

In this regard, claims 1 and 16 have been limited to the employment of Bacillus Calmette-Guerin (BCG) as the *Mycobacterium* as recited in non-rejected claims 7 and 19. As a consequence, claims 5 to 7 and 17 to 19 have been deleted. Claims 8, 11 and 12 have been amended to refer to BCG and the dependency of claims 13 and 20 has been amended consequentially. Having regard thereto, it is submitted that claims 1 to 6, 8 to 12, 16 to 18 and 23 to 25 are fully enabled and the rejection thereof under 35 USC 112, first paragraph, should be withdrawn.

The Examiner rejected claims 1 to 25 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner raised several issues in this regard:

(a) The Examiner considered claims 1 and 16 to be vague and indefinite with respect to the term "region of infection". This team has been modified to refer to "an area of infection" in both claims 1 and 16. Consequential revisions have been made to claims 11, 12 and 13. It is submitted that it is now clear that the claims are referring to the site of infection.

(b) The Examiner considered that the term "effective" renders claim 1 vague and indefinite. The Examiner considered it unclear for which purpose the composition is to be effective. It is submitted that it is quite clear that the composition is applied in an amount which is effective to treat the disease condition caused by papilloma virus. Nevertheless,

the phrase has been changed to refer to "a treatment dose". It is submitted that the language used is not indefinite.

(c) The Examiner objected to the terminology "tuberculosis complex" as used in claims 5 and 17. While denying there is any indefiniteness in the terminology, nevertheless claims 5 and 17 have been deleted having regard to the revisions to claim 1, rendering the rejection moot.

(d) The Examiner considered claim 8 to be vague and indefinite. No revision has been made to this claim with respect to the matter raised. The claim simply recites a specific treatment regime. The claim recites that there are from 1 to 30 treatments with a time interval between treatments of more than one of 1 to 30 days. The individual treatment dosages are 1 to 500 mg of BCG. It is submitted that the wording is entirely clear in scope.

(e) The Examiner considered claims15 to 22 to be vague and indefinite by the use of the term "about 1 to about 10 wt%". Claim 15 is dependent on claim 14 which recites that the salicylic acid is present in an amount of about 0.1 to about 50 wt% of the composition. A similar relationship exists between claims 21 and 22. Clearly, the ranges recites in subsidiary claims are on the same basis. However, these claims have been amended to refer to wt% of the composition.

(f) The Examiner objected to claims 24 and 25. However, these claims have been deleted having regard to their rejection under 35 USC 101, as discussed below.

Having regard to the revisions made to the claims and the above comments, it is submitted that all claims are clear in scope and hence the rejection of claims 1 to 25 under 35 USC 112, second paragraph, insofar as they remain in the application and in their amended forms, should be withdrawn.

The Examiner rejected claims 24 and 25 under 35 USC 101 as being in non-statutory form. These claims have been deleted thereby obviating the rejection.

The Examiner rejected claims 1 to 2, 5 to 6, 9 and 24 to 25 under 35 USC 102(b) as being anticipated by Herr et al.

As noted above, claims 5, 6, 24 and 25 have been deleted while claim 1 has been limited to the subject matter of claim 7, not the subject of this rejection. Nevertheless, the following comments are offered.

The present invention, as defined in amended claim 1, relates to the treatment of disease conditions caused by papilloma virus with BCG. The Herr et al reference is not concerned with the treatment of a papilloma virus disease condition but rather describes the treatment of superficial bladder tumors with topical instillation of BCG. No cream is used. Human papilloma virus is not associated with bladder carcinoma and bladder papillomas. In this regard, attention is directed to the enclosed PTO-1449 and the paper attached thereto. Our cheque in respect of the prescribed fee for submission of an IDS at this stage of prosecution is enclosed.

In the reference, the word "papilloma" is used to describe grade 1 papillary tumor when referring to superficial bladder tumors. There is a continuing debate about the classification of benign bladder lesions known as papillomas. The WHO defines papillomas as a single papillary (or wart-like) growth with 8 or less cell larger in normal-looking surface tissue. By contrast, most pathologists and urologists classify papilloma as a Grade 1 TCC (transient cell carcinoma) because of its tendency to recur and not invade muscle. Ta (papillary, noninvasive carcinoma) tumors are papillary (wart-like) in nature. They often look like pink cabbages and they may be present in groups. Ta tumors are confined to the inner surface of the bladder wall and are distinguished from T1 tumors because they have not broken through the basement (supporting) membrane. There is no association whatsoever between papillary urothelial carcinoma (sometimes called papillomas) and HPV-associated condyloma (warts).

Having regard to the above, it is submitted that none of the claims is anticipated by Herr et al and hence the rejection of claims 1 to 2, 5 to 6, 9 and 24 to 25, in their amended forms and insofar as they remain in the application, under 35 USC 102(b) should be withdrawn.

The Examiner rejected claims 1 to 23 under 35 USC 103(a) as being unpatentable over Herr et al in view of Morten.

The Herr et al reference has been discussed above in relation to the method of treatment claims. As discussed, Herr et al does not describe a treatment for a disease condition caused by papilloma virus, nor a composition for such specific purpose.

The Morten reference describes the provision of pharmaceutical compositions for topical application which essentially contain an anti-viral nucleoside analog for inhibiting viral replication of DNA viruses. The compositions may contain a keratolytic agent, which may be salicylic acid, as do the compositions claimed in claims 16 to 23. The compositions described in Morten are indicated to be useful in the treatment of a unclear of viral skin infections, including condylomata accuminata.

However, it is submitted that there is no motivation to modify the composition described by Morten et al to remove an essential component, namely an anti-viral nucleoside analog, and replace it with BCG. Having regard to the Herr et al reference, while such substitution may well give rise to a composition useful for the treatment of condylomata accuminata, such substitution would destroy the purpose of Morten, which is to provide a composition which functions by inhibiting viral replication of DNA viruses.

In addition, as noted earlier, Herr et al is not concerned with the treatment of a disease condition caused by papilloma virus. Hence, there would be no motivation to utilize BCG in a composition to treat such a disease condition.

Accordingly, it is submitted that claims 1 to 23 are patentable over the applied art and hence the rejection thereof, insofar as they remain in the application and in their amended forms, under 35 USC 103(a) as being unpatentable over Herr et al in view of Morten, should be withdrawn.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**."

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Prior to claim 1, insert the phrase:

"What we claim is:"

Claims 1, 3, 8, 11, 12, 13, 15, 16, 20 and 22 have been amended as follows:

1. (Amended) A method of treatment of a disease condition caused by papilloma virus, which comprises:

applying a treatment dose [an effective amount] of Bacillus Calmette-Guerin (BCG) [a *Mycobacterium*] to an area [the region] of infection.

3. (Amended) The method of claim 2 wherein the disease condition includes [include] cutaneous and genital warts in humans.

8. (Amended) The method of claim 1 wherein from about 1 to about 30 treatments of time interval from about 1 to about 30 days between treatments of more than one and the individual treatment dosage is from about 1 to about 500 mg of the BCG [*Mycobacterium*].

11. (Amended) The method of claim 1 wherein said BCG [*Mycobacterium*] is formulated with a keratolytic agent for topical application to the area [region] of infection.

12. (Amended) The method of claim 11 wherein said BCG [*Mycobacterium*] is formulated with said keratolytic agent as a cream for adherent application to the area [region] of infection.

13. (Amended) The method of claim 1 [7] wherein said BCG is formulated with powdered salicylic acid as an adherent cream for application to the area [region] of infection.

15. (Amended) The method of claim 14 wherein said salicylic acid is present in an amount of about 1 to about 10 wt% of the composition.

16. (Amended) A therapeutic composition for the treatment of a disease condition caused by papilloma virus, comprising a treatment dose [an effective amount] of Bacillus Calmette-Guerin (BCG) [a *Mycobacterium*] formulated with a keratolytic agent for topical application to an area [a region] of infection.

20. (Amended) The composition of claim 16 [19] wherein said keratolytic agent is powdered salicylic acid.

22. (Amended) The composition of claim 21 wherein said salicylic acid is present in an amount of about 1 to about 10 wt% of the composition.

Please cancel claims 5 to 7, 17 to 19, 24 and 25.